UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,697	04/12/2006	Carsten Olsen	10442.204-US	2080

25908 7590 10/02/2008

NOVOZYMES NORTH AMERICA, INC.
500 FIFTH AVENUE
SUITE 1600
NEW YORK, NY 10110

EXAMINER	
DESAI, ANAND U	

ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
10/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,697	OLSEN ET AL.	
	Examiner	Art Unit	
	ANAND U. DESAI, Ph.D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-70* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-54,58-60,64,65 and 67* is/are rejected.

7)☒ Claim(s) *66* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 55, 56, 57-60 (all drawn to non-elected species), 61-63, and 68-70.

DETAILED ACTION

1. This office action is in response to the amendment filed on June 30, 2008. Claims 30-49 have been cancelled. New claims 50-70 have been added.

2. Claims 55, 56, 57-60 (all drawn to non-elected species), and 68-70 are withdrawn because they are of the same scope of previously withdrawn claims 35, 36, 38, 39, 48 and 49.

3. Newly submitted claims 61-63 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the pending claims recite chemical nucleic acid sequences that were not part of the elected species that is the new claim is recited to claim an antibiotic selection marker, a resolvase site, and at least one transcription terminator located upstream of a gene.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 61-63 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Applicant is reminded that the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

5. Claims 50-54, 57-60(drawn to the elected species), and 64-67 are currently pending and are under examination.

Withdrawal of Rejections

6. The rejection of claims 30-34, and 37-39 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn based on the cancellation of the claims and the amendment to new claim 50 to cure the indefiniteness of the independent claim because the amplification unit is integrated in the genome of the bacterial host cell.

7. The rejection of claims 30-32, 34, and 37 under 35 U.S.C. 102(b) as being anticipated by Glenting et al. (Applied and Environmental Microbiology, 68(10): 5051-5056 (2002)) is withdrawn based on the cancellation of the claims and the amendment to claim 50 to recite the amplification unit is integrated in the genome of the bacterial host cell.

Pending Rejections

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 50-54, 64, 65, and 67 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-30 of U.S. Patent No. 6,762,040 B2 (previously cited). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent are drawn to a host cell produced by the method comprising two or more amplified copies of an amplification unit integrated into the host cell chromosome, wherein the method comprises the steps of: (a) providing a bacterial host cell wherein a chromosomal gene encoding at least one enzyme involved in the removal or UDP-galactose is non-functional, whereby the host cell is susceptible to inhibition by UDP-galactose endogenously produced by the host cell when the host cell is cultivated in a medium comprising galactose or a galaclose precursor; thereby rendering the host cell auxotrophic (b) introducing a nucleic acid construct into the host cell of step (a), the construct comprising an amplification unit, and said amplification unit comprising: i) an expression cassette comprising at least one copy of a gene of interest; and ii) an expressible copy of the chromosomal gene of step (a) or a partial non-functional copy of the chromosomal gene of step (a), wherein at least one copy of the amplification unit integrates into the host cell chromosome; (c) cultivating the host cell of step (b) in a medium comprising galactose or a galactose precursor, wherein the at least one chromosomally integrated copy of the amplification unit is duplicated or multiplied on the host cell chromosome; and (d) selecting a host cell comprising two or more chromosomally integrated amplified copies of the amplification unit. The claims are of overlapping scope.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 64 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Regarding claim 64, the term "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 112, 1st paragraph, Written Description

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 58-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims do not direct one of ordinary skill in the art to an amino acid structure that is at least 75% identical to *metE* sequence as currently claimed. The MPEP states that the purpose

of the written description requirement is to ensure that the inventor had possession, at the time the invention was made, of the specific subject matter claimed. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

MPEP § 2163 further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163 does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has a substantial variance, the disclosure must

describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad genus. Claim 58-60 are broadly generic to all possible modifications encompassed by the claims. The possible variations are enormous to any class of modified amino acid sequences. Since the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the 75% or greater identical sequences beyond those disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed

that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

16. Claims 50-54, 64, 65, and 67 are rejected under 35 U.S.C. 102(e) as being anticipated by Rasmussen (U.S. Patent 6,762,040 B2; previously cited).

17. Rasmussen discloses a host cell produced by the method comprising two or more amplified copies of an amplification unit integrated into the host cell chromosome, wherein the method comprises the steps of: (a) providing a bacterial host cell wherein a chromosomal gene encoding at least one enzyme involved in the removal or UDP-galactose is non-functional,

whereby the host cell is susceptible to inhibition by UDP-galactose endogenously produced by the host cell when the host cell is cultivated in a medium comprising galactose or a galaclose precursor; thereby rendering the host cell auxotrophic (b) introducing a nucleic acid construct into the host cell of step (a), the construct comprising an amplification unit, and said amplification unit comprising: i) an expression cassette comprising at least one copy of a gene of interest; and ii) an expressible copy of the chromosomal gene of step (a) or a partial non-functional copy of the chromosomal gene of step (a), wherein at least one copy of the amplification unit integrates into the host cell chromosome; (c) cultivating the host cell of step (b) in a medium comprising galactose or a galactose precursor, wherein the at least one chromosomally integrated copy of the amplification unit is duplicated or multiplied on the host cell chromosome; and (d) selecting a host cell comprising two or more chromosomally integrated amplified copies of the amplification unit. The expression vector can comprise a DNA molecule, linear or circular, that comprises a segment encoding a polypeptide of interest operably linked to additional segments that provide for its transcription. Such additional segments may include promoter (see e.g. col. 4, line 65 through col. 5, line 44). The term "an expressable copy of a chromosomal gene" is used herein as meaning a copy of the ORF of a chromosomal gene, wherein the ORF can be expressed to produce a fully functional gene product. The expressable copy may indeed be promoterless and expressed only by transcriptional read-through from a gene present upstream of the 5' end of the ORF (see col. 5, lines 38-41). Transcriptional read-through is intended to have the same meaning here as the generally recognized meaning in the art. One preferred embodiment of the invention relates to the method of the first, second, or third aspects, wherein the expressable copy of the chromosomal gene comprised in an

amplification unit integrated in the host cell chromosome has a reduced transcription level compared to the transcription level of the wild type gene of the host cell, preferably the transcription level is reduced with a factor of 100, preferably 50, more preferably 10, even more preferably 5, and most preferably with a factor of 2; preferably the expressable copy of the chromosomal gene comprised in the amplification unit is promoterless, more preferably the expressable copy of the chromosomal gene comprised in the amplification unit has a transcription terminator located upstream of the gene (see col. 17, lines 31-44). The host cell is inhibited from growth in the presence of galactose, because the gene encoding at least one enzyme involved in the removal of UDP-galactose is non-functional. The nucleic acid construct comprises an enzyme capable of preventing the inhibition of growth in the presence of galactose (see claim 19).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Objections

18. Claims 58-60 are objected to because of the following informalities:

19. The claims are incorporating essential material by way of an international application. Applicant is referred to 37 CFR 1.57 (c) "Essential material" may be incorporated by reference, but only by way of an incorporation by reference to a U.S. patent or U.S. patent application

publication, which patent or patent application publication does not itself incorporate such essential material by reference.

20. Claim 66 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Appropriate correction is required.

Conclusion

21. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI, Ph.D. whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

September 28, 2008
/ANAND U DESAI, Ph.D./
Examiner, Art Unit 1656